

Thermal Ablation vs Surgery for Localized Kidney Cancer: a Surveillance, Epidemiology, and End Results (SEER) Database Analysis

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OBJECTIVE	To evaluate contemporary national practice pattern trends in the use of thermal ablation (radiofrequency ablation and cryoablation) in the management of stage I renal cell carcinoma (RCC), and the factors that lead to using thermal ablation (TA) vs partial (PN) or radical nephrectomy (RN) in the United States.
METHODS	Within the Surveillance, Epidemiology and End Results (SEER) database, we identified subjects with T1-N0M0 RCC treated with either PN, RN, or TA between 2004 and 2007. Proportions, trends, and multivariable logistic regression models tested the predictors of the use of TA.
RESULTS	In total, 15,145 patients underwent a procedure for an RCC that was organ-confined and ≤ 7 cm. Of these, 578 underwent TA, 4402 underwent PN, and 10,165 underwent RN. On unadjusted analyses, patients who received TA were more likely to be older, single, have smaller tumor size, be diagnosed in more recent years, and have more unspecified histologic subtype and tumor grade. In multivariable adjusted analyses, single status ($P = .02$), male gender ($P = .01$), increasing age ($P < .01$), year of diagnosis ($P < .01$), and smaller tumor size ($P < .01$) were strong independent predictors of TA use compared with surgery (PN or RN). Further adjusted analyses showed no statistical difference in cancer-specific or overall survival between TA vs PN or RN.
CONCLUSIONS	TA use for stage I RCC increased over a relatively short period and was performed more commonly in patients of older age and with smaller tumor size. Longer follow-up is needed to assess the comparative effectiveness of TA vs surgery. UROLOGY 78: 93–98, 2011. © 2011 Elsevier Inc.

Currently, renal cell carcinoma (RCC) is most commonly diagnosed incidentally as the result of an imaging study performed for an unrelated complaint, leading to an increased detection of RCC.^{1–4} The detection of an incidental solid renal mass is a current clinical conundrum for the practicing physician. Once thought to be RCC, surgical series have shown that a portion of solid enhancing renal masses, particularly when small (≤ 4 cm), are in fact benign and may be left alone^{5,6}; even those masses found to be RCC, because they are detected incidentally, tend to be low grade⁶ by contrast, but not all are low grade and hence treatment may potentially be life-saving. Therefore, the manage-

ment of an incidentally detected solid renal mass is controversial.^{7,8} Initially, a thorough radiological evaluation (that may include a percutaneous biopsy) is recommended to determine whether the mass can be diagnosed as a benign entity. Once a probable diagnosis of RCC is achieved, management options include observation (also known as *active surveillance*), surgery, or thermal ablation (TA). Because incidentally detected solid renal masses are typically small and organ-confined, there is a shift toward nephron-sparing, and radical nephrectomy (RN) may be avoided.⁸ Compared with RN, partial nephrectomy (PN) has similar short- and long-term oncologic outcomes,^{4,7,9} reduced risk of progressive renal failure, and reduced risk of adverse cardiovascular events and overall mortality.^{10–12} As a result, the American Urologic Association (AUA) issued guidelines in 2009 for stage 1, small (≤ 7 cm) RCC, reaching a panel consensus that surgical excision by PN is a reference standard for the management of clinical T1 RCC, given the importance of preservation of renal parenchyma in order to avoid of chronic kidney disease (CKD).⁸

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Nevertheless, open PN can still be associated with substantial morbidity.^{10,13} Laparoscopic PN can provide more rapid recovery and less blood loss, but has been associated with an increased risk of major urologic complications and longer warm ischemia times when compared with the traditional open approach.¹⁴

Because of the potential morbidity associated with surgery, the use of thermal-based tissue-ablative techniques, such as cryoablation (CA) and radiofrequency ablation (RFA) have expanded considerably. Thermal ablation (TA) offers several advantages relative to surgery, including lower complication rates, shorter period of recovery, absence of an ischemic insult, and the potential for outpatient management,^{9,15} and these characteristics may be particularly appealing for patients with severe comorbidities. Although short-term results after TA have been encouraging, data remain limited; most studies report a relatively small number of patients and originate from large academic specialized medical centers. The purpose of our study was to evaluate contemporary US practice pattern trends in the management of stage I RCC and identify factors associated using ablative therapies (RFA and CA) vs surgery.

MATERIAL AND METHODS

Data

Our patient sample was obtained from the most recent Surveillance, Epidemiology and End Results (SEER) data comprised of 17 regional tumor registries established by the National Cancer Institute, which was released in May 2010. SEER is an authoritative source of information on population-based cancer characteristics and represents approximately one quarter of the US population.¹⁶ The SEER registry collects information on cancer incidence and survival in the United States as well as information regarding the site and extent of disease; the first course of treatment/procedure; and social, demographic and tumor-specific characteristics, with documented follow-up, including the date and cause of death.

Patient Selection

The SEER database was analyzed for renal cortical tumors diagnosed between 2004 (after the inception of TA) and 2007 that were coded as primary site “kidney, not otherwise specified” (International Classification of Diseases for Oncology, 2nd rev, topography code C64.9). On the basis of available histologic data, nonparenchymal tumors, such as urothelial carcinoma, and other nonrenal cortical tumors were excluded. We included only patients who underwent a procedure (surgery, consisting of RN [codes 40, 70, 80], PN [code 30], and ablation procedures using CA [codes 13, 23] or RFA [code 15]) for their renal tumor. Since 2004, RFA and CA have been identified distinctly within SEER, and therefore the year 2004 was chosen as the starting point for the study. Patient demographic variables included age, gender, race (Caucasian, African American, or other), geographic location, marital status, urban/rural, and zip code education. Tumor-specific variables included size, histologic subtypes (clear cell, papillary, chromophobe, and unspecified/adenocarcinoma) and Fuhrman grade. The cohort included patients who had tumors that measured ≤ 7 cm in

greatest dimension (stage I RCC), and this resulted in a final study group of 15,145 patients.

Statistical Analysis

Logistic regression was used to identify characteristics associated with treatment type. Univariate survival analyses were performed with Kaplan-Meier log-rank tests; multivariate survival analyses were performed with proportional hazards regressions. All statistical analyses were performed in SAS 9.2 (SAS Institute, Cary, NC).

RESULTS

Baseline Characteristics

Of 15,145 patients who underwent a procedure for a renal tumor that was ≤ 7 cm between 2004 and 2007, 578 underwent TA (RFA or CA), 4402 underwent PN, and 10,165 underwent RN. Table 1 illustrates the characteristics of the 578 patients who underwent TA, as compared to patients who underwent PN or RN during the same time period. On unadjusted analyses, there were statistically significant differences in term of age, year of diagnosis, marital status, tumor size (using the 4-cm cut-off or as a continuous variable), tumor histology, and grade between TA and both PN and RN. Patients who received TA were in general more likely to be older, single, have smaller tumors, be diagnosed in more recent years, and have more unspecified histologic subtype and unknown tumor grade. Figure 1 shows the trend of TA and PN use from 2004 to 2007, compared with RN.

Adjusted Predictors of Thermal Ablations vs Partial Nephrectomy or Radical Nephrectomy

First, we compared using a multivariable analysis, the clinical variables that predicted whether patients were treated with TA vs PN. Overall, male gender, increasing age, year of diagnosis, and smaller tumor size predicted the selection of ablative therapies (Table 2).

Second, on multivariable analysis, we compared the clinical variables that predicted receiving TA vs RN. Overall, increasing age, year of diagnosis, single status, decreasing tumor size, and lower education also predicted the use of ablative therapies (Table 2).

Finally, when comparing TA with any surgery (either RN or PN), the multivariable results showed the similar trends overall in term of predictors of TA vs surgery (Table 2).

Oncologic Outcomes of TA vs Surgery

Median follow-up for the entire cohort was 21.2 months. One- and 2-year cancer-specific survival (CSS) was 99.4% and 98.0% for TA, respectively, 99.6% and 99.3% for PN, respectively; and 98.9% and 98.0% for RN, respectively. On univariate analysis, TA showed significantly lower CSS than PN (1.6% vs 0.7%; $P = .025$), but not compared with RN (1.6% vs 1.8%; $P = .7$). However, when adjusted for several variables, including age, tumor size, gender, race, marital status, and geographic

Table 1. Baseline characteristics in 15,145 patients diagnosed with stage I renal cell carcinoma (RCC) stratified by treatment modality: thermal ablation (TA), partial nephrectomy (PN), and radical nephrectomy (RN)

	Ta	PN	P Values	RN	P Values
Total n = 15,145	n = 578 (%)	n = 4,402 (%)	TA vs PN	n = 10,165 (%)	TA vs RN
Gender					
male	356 (61.6%)	2710 (61.6%)	.99	5999 (59.0%)	.22
Female	222 (38.4%)	1692 (38.4%)		4166 (41.0%)	
Age (yo)					
<40	9 (1.6%)	362 (8.2%)	<.001	523 (5.2%)	<.001
40–49	37 (6.4%)	776 (17.6%)		1490 (14.7%)	
50–59	104 (18.0%)	1234 (28.0%)		2679 (26.4%)	
60–69	149 (25.8%)	1196 (27.2%)		2720 (26.8%)	
70–79	185 (32.0%)	702 (16.0%)		2064 (20.3%)	
≥80	94 (16.3%)	132 (3.0%)		689 (6.8%)	
Race					
White	492 (85.1%)	3695 (83.9%)	.4	8507 (83.7%)	.48
African American	55 (9.5%)	405 (9.2%)		984 (9.7%)	
Other	31 (5.4%)	302 (6.9%)		674 (6.6%)	
SEER region					
Urban	515 (89.7%)	3949 (90.0%)	.84	8897 (87.8%)	.16
Rural	59 (10.3%)	439 (10.0%)		1240 (12.2%)	
Year of diagnosis					
2004	82 (14.2%)	912 (20.7%)	.001	2318 (22.8%)	<.001
2005	123 (21.3%)	975 (22.2%)		2514 (24.7%)	
2006	173 (29.9%)	1128 (25.6%)		2681 (26.4%)	
2007	200 (34.6%)	1387 (31.5%)		2652 (26.1%)	
Marriage status					
Single	234 (40.5%)	1467 (33.3%)	<.001	3675 (36.2%)	.035
Married	344 (59.5%)	2935 (66.7%)		6490 (63.9%)	
Tumor size					
≤4 cm	537 (93.4%)	3763 (85.9%)	<.001	5453 (53.8%)	<.001
4.1–7 cm	38 (6.6%)	618 (14.1%)		4693 (46.3%)	
Histology					
Clear cell cancer	246 (42.6%)	2409 (54.7%)	<.001	6322 (62.2%)	<.001
Papillary	76 (13.2%)	789 (17.9%)		1050 (10.3%)	
Chromophobe	15 (2.6%)	301 (6.8%)		560 (5.5%)	
Adenocarcinoma (nonspecified)	241 (41.7%)	903 (20.5%)		2233 (22.0%)	
Tumor grade					
I & II	257 (44.5%)	3159 (71.8%)	<.001	6736 (66.3%)	<.001
III	30 (5.2%)	651 (14.8%)		1948 (19.2%)	
IV	1 (0.2%)	46 (1.0%)		248 (2.4%)	
Unknown	290 (50.2%)	546 (12.4%)		1233 (12.1%)	

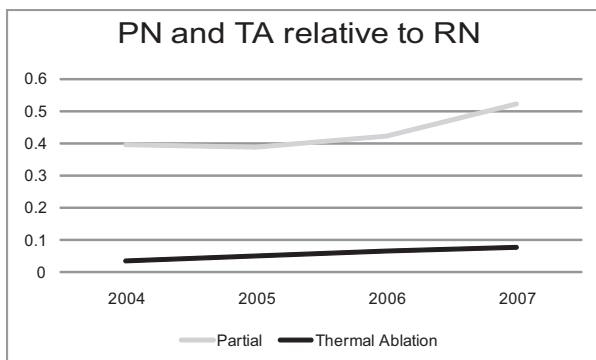


Figure 1. Trends in the use of thermal ablation (TA) or partial nephrectomy (PN) compared with radical nephrectomy (RN) for stage 1 renal cell carcinoma (RCC).

location, there was no difference in CSS among patients who underwent TA vs PN (hazard ratio 0.6, 95% CI 0.28–1.28; $P = .2$).

Similarly, 1-year and 2-year overall survival (OS) were 96.4% and 92.5% for TA, respectively; 98.8% and 97.6% for PN, respectively; and 97.2% and 94.6% for RN, respectively; and on multivariable analyses and when adjusted for several variables, including age, tumor size, year of diagnosis, gender, race, marital status, and geographic location, there was no difference noted in OS among patients who underwent TA vs PN ($P = .32$) or TA vs RN ($P = .73$) by treatment type.

COMMENT

To our knowledge, our study is the first population-based study to evaluate usage trends and practice patterns for ablative therapies for RCC in the United States. Our paper has several important findings worth discussing:

First, although the use of TA and PN are both increasing, only one third of patients with stage I RCC actually underwent either TA or PN (nephron-sparing proce-

Table 2. Adjusted model demonstrating independent patient factors associated using TA compared with PN, RN, or any surgery (RN or PN)

	OR (95% CI)		OR (95% CI)		OR (95% CI)	
	TA vs PN	P Values	TA vs RN	P Values	TA vs any surgery (PN or RN)	P Values
Gender						
Female	Referent		Referent		Referent	
male	1.30 (1.08–1.56)	.05	1.16 (0.96–1.41)	.12	1.27 (1.06–1.53)	.01
Age (y)						
< 40	Referent		Referent		Referent	
40–49	1.55 (0.74–3.24)	.25	1.97 (0.94–4.13)	.07	1.7 (0.8–3.6)	.14
50–59	2.49 (1.25–4.99)	.010	3.45 (1.73–6.91)	<.001	2.9 (1.5–5.8)	.002
60–69	3.44 (1.73–6.82)	<.001	5.13 (2.59–10.19)	<.001	4.1 (2.1–8.1)	<.001
70–79	5.66 (2.86–11.18)	<.001	10.90 (5.50–21.58)	<.001	7.5 (3.8–14.7)	<.001
≥80	9.13 (4.52–18.4)	<.001	29.66 (14.49–60.69)	<.001	14.2 (7.1–28.5)	<.001
Race						
White	Referent		Referent		Referent	
African American	1.09 (0.80–1.47)	.6	1.1 (0.8–1.6)	.42	1.1 (0.8–1.5)	.48
Other	0.84 (0.57–1.24)	.38	0.8 (0.6–1.2)	.37	0.8 (0.6–1.2)	.38
Year of diagnosis (continuous)	1.27 (1.17–1.37)	<.001	1.2 (1.1–1.3)	.001	1.2 (1.1–1.3)	<.001
Marriage status						
Single	Referent		Referent		Referent	
Married	0.83 (0.69–1.00)	.05	0.8 (0.6–0.9)	.010	0.8 (0.7–1.0)	.02
Tumor size						
≤4 cm	Referent		Referent		Referent	
4.1–7 cm	0.08 (0.06–0.11)	<.001	0.40 (0.28–0.57)	<.001	0.1 (0.08–0.16)	<.001
Density						
Urban	Referent		Referent		Referent	
Rural	0.74 (0.54–1.01)	.055	0.8 (0.6–1.1)	.20	0.7 (0.5–1.0)	.06
Education						
% College degree	1.00 (0.99–1.01)	.37	0.98 (0.97–0.99)	<.001	0.99 (0.98–1.0)	.05

OR = odds ratio; CI = confidence interval.

dures). Despite the reported oncologic equivalence and benefits of nephron-sparing procedures, two thirds of patients underwent RN. Even when restricting the analysis to small (≤ 4 cm) renal tumors, more than half of patients received RN. Our findings are consistent with a prior study of SEER registries up to 2001 that indicated only a minority of patients with small tumors underwent a nephron-sparing approach, ie, PN.¹⁷ A more recent evaluation of SEER registries from 1999–2006 found that 65% of patients underwent RN.¹⁸ Dulabon et al specifically analyzed renal tumors ≤ 4 cm and found that PN was used more frequently than in the past, but remained underused.¹⁸

Second, we found older age to be associated with TA use. Others have found older age (with likely a higher risk of comorbidities) to be associated with increased usage of TA,¹⁹ possibly because of the perceived short-term equivalent oncologic efficacy for patients undergoing TA with less procedure-related morbidity than surgery.²⁰

Third, smaller tumor size was associated with an increased use of TA vs PN or RN. Kunkle et al also found smaller lesions to be associated with greater use of TA vs surgery.¹⁹ Moreover, in our TA cohort, 93% of stage I patients had tumors that were ≤ 4 cm, which is consistent with the literature.^{15,21,22} The long-term

effectiveness of TA is unknown, but data suggest that the smaller the tumor, the more likely ablation is to be successful.^{19,20,23}

Fourth, in our multivariable analyses, there was no difference in CSS or OS among patients who underwent TA vs PN. These findings are similar to a recent meta-analysis by Kunkle et al that found no significant difference in CSS among patients who underwent PN and TA.²⁰ However, they found RFA and CA patients to have an 18-fold and 7-fold increased risk of local recurrence when compared with those who underwent PN, respectively. However, several confounding variables preclude determination of TA inferiority. These include the portion of biopsy-proven cancers in each group and whether the ablation was done percutaneously, open, or laparoscopically. Kunkle et al's analysis considered all ablations together, regardless of their approach. Finally, percutaneous ablations can be repeated more easily than PN, and in fact are repeated in practice.⁹ Hence the effectiveness of TA might be considered after all treatments, not simply, as in the Kunkle analysis, the first treatment procedure. Although the short-term equivalent oncologic efficacy for TA has been published previously^{19,20} and confirmed in our study, we could not assess (1) the rate of local recurrence or the odds of requiring another ab-

lation procedure for the same tumor, and (2) comorbidity status in this population, which may have a significant impact on the OS findings.

Fifth, almost half of the patients undergoing TA did not have the treated tumor's histologic subtype or Fuhrman grade specified. This was probably because a biopsy was not performed before TA, or if it was performed, the histologic subtype or the tumor grade could not be determined. This was also a problem in the Kunkle et al and Hui et al analyses,⁹ and was indeed a limitation for all retrospective studies that have attempted to examine the comparative effectiveness of definitive therapies for renal masses. It is therefore important to emphasize that in clinical practice, the management of renal masses begins with a thorough radiologic evaluation to maximize the chance that only cancers are treated. Percutaneous biopsy is playing a larger role⁷ and may be used to reduce the number of benign tumors treated inadvertently. Overall, it is important to understand that the current available data, including SEER, likely includes benign masses and therefore does not reflect only the relative effectiveness of treating cancers. Nevertheless these data can be helpful in counseling patients and selecting follow-up imaging strategies.

Our study has several additional limitations that should be acknowledged. Our findings must be interpreted in the context of the study design. First, although SEER is derived from 17 registries, it may not be representative of practice patterns in non-SEER regions. Second, our population included stage I RCC patients that were defined as having tumors ≤ 7 cm, to exclude larger and more advanced tumors where TA or PN are not usually performed. Third, although we were able to capture practice trends and oncologic outcomes from 2004 to 2007, these data may not represent current practice trends after implementation of more recent practice guidelines, such as the dedicated 2009 AUA guidelines regarding the management of clinical stage 1 renal mass.⁸ Fourth, the follow-up of 21 months in our study is short, especially for the oncologic outcome of CSS and OS. Fifth, management options for small kidney masses include (in addition to AT or surgery) active surveillance with delayed intervention upon growth. This strategy is an attractive option in high surgical-risk and older patients, but could not be explored in our study. Sixth, because of the relatively small number of patients undergoing TA compared with surgery, we did not attempt to compare the effectiveness of RFA with CA; our purpose was to evaluate practice patterns of AT vs surgery. Seventh, our cohort is not able to differentiate between TA performed by percutaneous vs laparoscopic approach. Finally, this study did not evaluate the relative safety of the 2 groups of procedures and similarly did not explore their cost-effectiveness; these will be the subjects of future studies.

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EDITORIAL COMMENT

The landscape of kidney cancer surgery continues to evolve. Throughout the last decade, nephron-sparing surgery (NSS), particularly partial nephrectomy (PN), has become the treatment of choice at tertiary care centers in the United States for localized kidney tumors. Despite the renal function advantages and equivalent oncologic outcomes of PN, this study and other similar studies point out that radical nephrectomy (RN) remains the most common treatment for newly diagnosed localized kidney tumors across the United States.¹

An alternative NS approach to PN that has emerged recently is the use of thermal ablatable (TA) techniques such as cryotherapy and radiofrequency ablation.² Such techniques are generally less invasive (particularly when performed percutaneously), technically less challenging, and associated with fewer procedure-related complications, making TA surgeries attractive for older and sicker patients with incidentally diagnosed small renal masses. Critics of such approaches, however, stress the limited oncologic data (short-term follow-up, lack of histologic diagnosis before treatment) as well as inferior recurrence rates when compared with PN.³ Furthermore, with increasing acceptance of observation as an alternative for the management of small renal tumors, the advantages of TA, particularly in the elderly or sick patient, remain uncertain.

The investigators in this study used the SEER Cancer Registry to examine the practice patterns and use of TA for the treatment of localized renal masses. During the study period (2004-2007), fewer than 4% of patients underwent TA for tumors <7 cm. Not surprisingly, TA was more likely to be used in older patients, in smaller tumors, and in tumors diagnosed in

recent years compared with PN or RN. In addition, nearly half of all patients undergoing TA were treated without complete data on histologic subtype and/or tumor grade. Interestingly, gender appeared to be predictive of treatment type, an observation that was also seen when using the same dataset comparing PN with RN.¹

In addition to reporting treatment trends of TA therapies, the investigators also examined cancer-specific and overall survival outcomes for TA techniques. The survival data, however, must be interpreted with caution. The authors appropriately point out significant limitations of these results because of having a very short median follow-up (21.2 months), no information on comorbid conditions, and a significant lack of pathologic data in the TA cohort.

The treatment paradigm of newly diagnosed renal tumors continues to slowly change across the United States. Despite the fact that RN continues to be the treatment of choice for most newly diagnosed kidney tumors, the use of PN is rising. It appears that use of TA is also rising, particularly in older patients and patients with smaller tumors. Over time, however, these same patients may ultimately be served best by surveillance or by no treatment at all.

Currently, the appropriate indications and the benefits of TA are unclear. Therefore, clinicians should responsibly and discerningly use TA and carefully weigh the risks and benefits before selecting patients for this burgeoning treatment modality.

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